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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,244	10/30/2001	Guillermo J. Tearney	00786-443001 / MGH 1542.1	4538
26161	7590	03/08/2005	EXAMINER SHAW, SHAWNA JEANNINE	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,244	Applicant(s) TEARNEY ET AL. 	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 39-43 and 62-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 39-43, 62-69 and 72-81 is/are rejected.
- 7) ☒ Claim(s) 70 and 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-25, 27 and 39-43 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 10, 12, 14-20 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimnyakov et al. "Spatial speckle correlometry in applications to tissue structure monitoring" of record.

Zimnyakov et al. teach temporally correlating dynamic speckle patterns obtained at time intervals sufficient to detect Brownian and cellular motion (pp. 5596 and 5601 also disclose 50µs scanning intervals) in order to monitor changes in tissue structure (pp. 5594-95).

3. Claims 1-10, 12, 21, 22, 24, 25, 39 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchitto et al.

Regarding claims 1-3, 5, 6, 10, 12, 18, 21, 22, 24, 25, 39 and 75, Marchitto et al. disclose a method for analyzing subsurface (internal) anatomical structures including: illuminating tissue with coherent (laser) light; receiving reflected light and forming speckle patterns; and analyzing changes in the speckle patterns to measure changes caused by microscopic motion of (e.g., red blood cells) within the tissue [0038].

Regarding claim 2, the red blood cells inherently undergo Brownian motion. Further regarding claims 18 and 20, Marchitto et al. disclose detecting built up speckle patterns to deduce structural characteristics such as blood vessels. Further regarding claims 4, 21, 22, 24 and 25, Marchitto et al. disclose compensating for motion via heartbeat monitoring [0031] and/or optionally coupling to a patient via supportive arms (fig. 9).

Regarding claims 7-9, Marchitto et al. disclose performing the imaging technique with an endoscope [0063], [0065], [0068].

Regarding claim 39, Marchitto et al. disclose a method for analyzing subsurface (internal) anatomical structures including: illuminating tissue with coherent (laser) light; receiving reflected light and forming speckle patterns; analyzing changes in the speckle patterns to measure changes caused by microscopic motion of (e.g., red blood cells) within the tissue; and deducing structural characteristics (e.g., blood vessels) [0038].

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. or Zimnyakov et al. of record.

Regarding claim 11, Marchitto et al. and Zimnyakov et al. do not explicitly address a superluminescent diode, however, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a superluminescent diode, because Applicant has not disclosed that such a light source provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the coherent light sources of Marchitto et al. or Zimnyakov et al. detect speckle changes caused by microscopic motion of objects in tissue.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchitto et al.

Regarding claim 23, although Marchitto et al. compensates for patient motion, Marchitto et al. does not explicitly address compensating for peristalsis. However, at

the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to compensate for peristaltic motion, because Applicant has not disclosed that such compensations provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the invention of Marchitto et al. which compensates for general patient motion via heartbeat monitoring, physical coupling and/or mathematical correction.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. in view of Facchini et al. "An endoscopic system for DSPI" of record.

Regarding claim 13, Marichitto et al. differs from the claimed invention in that near field speckle is not explicitly addressed. Facchini et al. demonstrate an established endoscopic system for digital speckle pattern interferometry for obtaining speckle patterns *in situ* in real time wherein changes a few tenths of a micron can easily be detected (p. 27, 29). Facchini et al. further disclose imaging either near-field (i.e., probe-object distances between 0-3cm) or far-field (3-20 cm) speckle, however indicates that the resolution decreases as the distance between the probe and object is increased (p. 28). It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to detect speckle data from directly adjacent the tissue as taught by Facchini et al. with the invention as taught by Marichitto et al. to obtain better resolution and as is known in the art.

7. Claims 14-20, 27 and 72, are rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. in view of Vachon et al. of record.

Regarding claims 14-20, Marichitto et al. differs from the claimed invention in that the analysis of the speckle patterns is not discussed in detail. Vachon et al. demonstrates that it is known to digitize and quantitatively correlate speckle patterns to a reference pattern (col. 1 lines 49-68 and col. 2 lines 39-45). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to correlate the speckle pattern to a reference as taught by Vachon et al. in the invention as taught by Marichitto et al. to obtain quantitative information with respect to the structure of the blood vessels as is well known in the art.

Regarding claims 27 and 72, although Marichitto et al. monitors blood flow in vessels, Marichitto et al. differs from the claimed invention in that detection of atherosclerotic plaque is not addressed explicitly. Vachon et al. generally demonstrates that it is well established to use speckle data to detect and characterize the status of atherosclerotic plaques in vessels (fig. 3). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use the obtained speckle data of Marichitto et al. to detect the presence of atherosclerotic plaques in the vessels as taught by Vachon et al. as is well known in the art and to caution the surgeon before advancement of a probe in the vessel.

8. Claims 40, 62-64, 68, 73, 74, 77, 79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. in view of Vachon et al. and further in view of Moreno et al. '743.

Regarding claims 40, 62-64, 68, 73, 74, 77, 79 and 81, although Marichitto et al. and Vachon et al. disclose analyzing cellular motion and vessel structure, Marichitto et al. and Vachon et al. differ from the claimed invention in that a determination of

thickness or collagen content of the detected fibrous plaques is not specifically addressed. Moreno et al. demonstrates that such markers are commonly known indicators of atherosclerotic plaque vulnerability (col. 20 lines 59-67 and col. 27 lines 39-46). It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to determine fibrous cap thickness and collagen content in the invention as taught by Marichitto et al. in view of Vachon et al. to accurately characterize atherosclerotic plaque and assess its vulnerability as is well known in the art. Furthermore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to calculate the thickness as a function of $(x_0^2 + y_0^2)^{1/2}$, because Applicant has not disclosed that such a function provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the time constant function of Boas et al. since both quantitatively measure spatial displacement.

9. Claims 41-43 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. in view of Vachon et al. of record and further in view of Moreno et al. in view of Boas et al. "Diffusing temporal light correlation for burn diagnosis" of record.

Regarding claims 41-43 and 65-67, the above mentioned inventions differ from the claimed invention in that comparison to a mathematical simulation model is not addressed explicitly. Boas et al. provides the general teaching of comparing optical tissue properties (taking into account the decorrelation rate) to mathematical simulation models such as Monte Carlo and diffusion theory to more easily and accurately predict

and derive tissue structure data on a microscopic level (p. 468-472 and 475). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to compare the optical speckle data of Marichitto et al. in view of Vachon et al. with mathematical simulation data as taught by Boas et al. to verify results and to derive more accurate tissue structure data on a smaller scale.

7. Claims 69, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marichitto et al. in view of Vachon et al. and further in view of Moreno et al. in view of Loree et al. "Mechanical Properties of Model Atherosclerotic Lesion Lipid Pools" of record.

Regarding claims 69, 78 and 80, the above mentioned inventions differ from the claimed invention in that viscosity is not specifically addressed. Loree et al. demonstrates that biomechanics such as lipid pool viscosity and elasticity are known indicators of plaque vulnerability. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to assess viscosity as taught by Loree et al. in the invention as taught by Marichitto et al. in view of Vachon et al. to accurately characterize the plaque and assess its vulnerability as is well known in the art.

Allowable Subject Matter

8. Claims 26, 70 and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

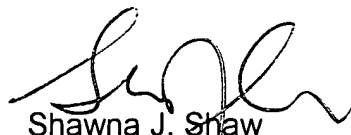
Conclusion

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (571) 272-4743. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
Art Unit: 3737
02/10/2005